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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/647,948  | 08/26/2003  | Harvey Jay           | J07-004              | 4553             |
| 7590  | 09/10/2008  |                      | EXAMINER             |                  |
| R. Neil Sudol<br>714 Colorado Avenue<br>Bridgeport, CT 06605-1601 |             |                      | JOHNSON III, HENRY M |                  |
|   |             |                      | ART UNIT             | PAPER NUMBER     |
|   |             |                      | 3739                 |                  |
|   |             |                      | MAIL DATE            |                  |
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|   |             |                      | DELIVERY MODE        |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/647,948             | JAY, HARVEY         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Henry M. Johnson, III  | 3739                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 July 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 68,73-77,86,94,95 and 105-118 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 68,73-77,86,94,95 and 105-118 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 26 August 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

***Response to Arguments***

Applicant's arguments filed July 7, 2008 have been fully considered but they are not persuasive.

Method claims are examined by evaluation of the positively cited manipulative steps that are directly controllable by person doing the treatment. Periodically applying pulses of EMR is such a manipulative step. How the body or tissue reacts is controllable only by the selection of the parameters of the EMR. The specific intended result of the radiation is interpreted by the examiner as a new use for a method of irradiation tissue with EMR. New use is not among categories of patentable inventions specified in 35 U.S.C. § 101 (Ex parte PFEIFFER, 135 USPQ 31 (Bd. Pat. App. & Int. 1961). If a reference provides irradiation of tissue with overlapping parameters, it must inherently yield the same result. The claims indicate the EMR parameters are selected to achieve a specific result, however, few defined parameters are cited in the claims, nor is a step for such selection. Thus the examiner must use those broad parameters disclosed in the specification or assume that such selection is within the capabilities of a skilled artisan. It is also noted, that multiple embodiments are disclosed with widely varying parameters with none having any unexpected or unpredictable results. Thus, the selection of pulse duration, pulse interval, pulse rate, etc., would combine to yield a fluence to the target tissue as is well known in the art. It is noted further, that the specification discloses how skin characteristics impact the treatment result, yet no method step including this additional (critical?) parameter is claimed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 110 and 111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Isolated wavelengths are not included in the original disclosure. While a single wavelength could be interpreted as an isolated wavelength, the use of the term as a basis for patentability requires original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73-77, 86 and 94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 is indefinite as the term "more frequently" is a relative term without bounds.

Claim 86 recites the limitation "said source of Xray or ultraviolet radiation" in lines 2-3.

There is insufficient antecedent basis for this limitation in the claim.

Claim 94 is indefinite as the term "more frequently" is a relative term without bounds.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 68, 73-77, 94, 95 and 105-118 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,676,655 to McDaniel. McDaniel teaches a method that applies electromagnetic radiation (EMR) to tissue using electromagnetic radiation with wavelengths from about 300 nm to about 1600 nm, and pulse durations from about 0.1 femtoseconds to about 100 seconds, interpulse delays between from about 0.1 to about 1000 milliseconds, and the energy fluence received by said tissue is less than about 10 J/cm<sup>2</sup> (Col. 2, lines 28-34). These parameters overlap those of the Applicant's disclosure to achieve the claimed result and therefore must be interpreted as yielding the same results. McDaniel teaches intervals between treatments can be as long as hours, days, weeks, months, etc (Col. 17, lines 28-29), thus teaching periodic treatments. The method of treatment comprises the step exposing tissue to the light of the stated parameters (Col. 2, lines 25-27). McDaniel teaches the use of porphyrin as an excellent topical (exogenous) composition with superior optical properties for acting as a chromophore to enhance low- intensity light therapies (Col 22, line 33-37). The absorption of various wavelengths and selected chromophores and body structure is disclosed as a wavelength selection criteria.

Method claims must be examined by evaluation of the positively cited manipulative steps that are directly controllable by person doing the treatment. Periodically applying pulses of EMR is such a manipulative step. How the body or tissue reacts is controllable only by the selection of the parameters of the EMR. The specific intended function as a result of the radiation is interpreted by the examiner as a new use for a method of irradiation tissue with EMR. New use is not among categories of patentable inventions specified in 35 U.S.C. § 101 (Ex parte PFEIFFER, 135 USPQ 31 (Bd. Pat. App. & Int. 1961)).

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The application of the EMR prior to, during or after exposure is not relevant as not positive step of exposing the tissue to Xray or ultraviolet radiation is cited. The actual manipulative step of applying would not be different at different times.

Regarding claim 77, the manner of exposure to Xray or ultraviolet radiation has no impact on the manipulative step.

Regarding claims 105 and 115, McDaniel teaches that ultrasound (mechanical wave energy) may be used therapeutically to interact directly with the agent or the agent-tissue complex to produce the desired damaged target tissues (to be used alone or in combination with laser or non-laser light sources)(Col. 6, line 66 to Col. 7 line 3).

Regarding claim 106, McDaniel discloses low energy electromagnetic fields can be used alone or in combination with photomodulation (Col. 15, lines 55-60).

Regarding claims 110 and 111, McDaniel uses LEDs as the EMR source and such would include at least the single wavelength of one of such LEDs.

Regarding claim 118, McDaniel clearly provides wavelengths that overlap those claimed.

### ***Allowable Subject Matter***

Claim 86 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 5:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Henry M. Johnson, III/  
Primary Examiner, Art Unit 3739

/HMJ/  
9/7/2008